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01/11/24

WHO Prequalifies Next-Generation Oral Polio Vaccine + More

The Defender's Big Pharma Watch delivers the latest headlines related to pharmaceutical companies and their products, including vaccines, drugs, and medical devices and treatments. The views expressed in the below excerpts from other news sources do not necessarily reflect the views of The Defender. Our goal is to provide readers with breaking news that affects human health and the environment.

By The Defender Staff

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WHO Prequalifies Next-Generation Oral Polio Vaccine

CIDRAP reported:

> The World Health Organization (WHO) recently prequalified the novel oral poliovirus vaccine type 2 (nOPV2), the first time the group has ever prequalified a vaccine that is being used under the emergency use listing, the Global Polio Eradication Initiative (GPEI) announced yesterday.
>
> Rollout of the new vaccine began in March 2021, and nearly 1 billion doses have already been administered across 35 countries. WHO prequalification, though, paves the way for more countries to receive the vaccine, which has played a key role in stemming outbreaks involving type 2 variant poliovirus (cVDPV2).
>
> The vaccine's maker is Bio Farma Indonesia and regulators in Indonesia have fully licensed it. It was developed by an international consortium that included the Bill and Melinda Gates Foundation, the United Kingdom's National Institute for Biological Standards and Controls (NIBSC), the U.S. Centers for Disease Control and Prevention, the U.S. Food and Drug Administration, PATH, and the University of California at San Francisco.
>
> Oral polio vaccine (OPV) is widely used in campaigns in lower-resource countries because it is easy to store and transport and easy to administer. However, the attenuated virus in the oral vaccine can mutate and become virulent again, especially in settings where uptake is low.

Contributors to Psychiatry's Bible, the DSM-5, Got $14 Million From Industry

STAT News reported:

> Amid ongoing concerns over conflicts of interest, a new study found that 60% of the physicians who served as panel and task force members for the American Psychiatric Association's official manual of psychiatric disorders received payments from industry totaling more than $14 million. And the authors argue the findings raise questions about the editorial independence of the reference book.
>
> The analysis examined financial relationships between industry and 92 U.S.-based physicians who helped assemble a recent revision of the Diagnostic and Statistical Manual of Mental Disorders, which is often referred to as the bible of psychiatry. This latest revision, known as the DSM-5-TR, was prepared between 2016 and 2019, and published in 2022.
>
> The researchers found that of the 55 physicians with ties to a pharmaceutical company, 91% accepted food and beverages, and 69% received compensation for travel and consulting, according to the analysis published in the BMJ. Half of the physicians received research funding, although the $9.9 million that was paid out represented 70% of the total amount of money paid to the physicians.

The Overdose Crisis Among U.S. Adolescents

The New England Journal of Medicine reported:

> Every week in 2022, the equivalent of a high school classroom's worth of students — an average of 22 adolescents — died of drug overdoses in the United States, according to data from the Centers for Disease Control and Prevention (CDC).
>
> Drug overdoses and poisonings are now the third-leading cause of pediatric deaths in this country, after firearm-related injuries and motor vehicle crashes.
>
> Although drug-related mortality among adults has risen steadily for multiple decades, adolescents had been largely insulated from these increases until the second half of 2019. After more than a decade of holding relatively steady, overdose deaths among adolescents 14 to 18 years of age more than doubled between August 2019 and March 2020 (see graph). Since then, this crisis has further intensified, with 5.2 deaths per 100,000 adolescents in 2022.
>
> An important driver of increasing risk is the widespread availability of counterfeit pills containing illicit fentanyl. Fentanyl is now involved in at least 75% of adolescent overdose deaths. Although fentanyl-associated deaths in the general population began to rise sharply in 2013, adolescent deaths weren't substantially affected until 2019.

Weight Loss Drug Windfall Attracts Pharma Companies

Reuters reported:

> Pharmaceutical executives from Amgen (AMGN.O) to Pfizer (PFE.N) are plotting to break into the lucrative obesity market by developing or cutting deals to acquire better drugs that will compete with Novo Nordisk's (NOVOb.CO) Wegovy and Zepbound from Eli Lilly (LLY.N).
>
> At stake is a market that is now estimated to reach $100 billion at a minimum by the end of the decade, as consumers flock to the new treatments that have been shown to reduce weight by as much as 20%. Drugmakers are testing these drugs for other health benefits such as lowering cardiovascular disease risk and obstructive sleep apnea.
>
> Amgen has an experimental dual mechanism obesity drug in mid-stage trials it hopes will have fewer side effects with less frequent dosing than Wegovy or Zepbound, Chief Scientific Officer Jay Bradner told Reuters at the annual JPMorgan health conference in San Francisco this week.
>
> German drugmaker Boehringer Ingelheim is developing an obesity treatment with Danish biotech Zealand Pharma (ZELA.CO) that targets GLP-1 as well as another hormone called glucagon. "I think we may be the first to bring a GLP-1/glucagon receptor agonist (to market)," said Boehringer's head of discovery research Clive Wood. By targeting glucagon, the drug also increases energy expended.
>
> Merck (MRK.N) and small biotech Altimmune (ALT.O) have similar drugs in development.

U.S. FDA Allows Import of Syphilis Drug to Address Shortages

Reuters reported:

> The U.S. Food and Drug Administration will temporarily allow the import of a syphilis drug made by France's Laboratoires Delbert, the company said on Wednesday. Laboratoires Delbert said it was coordinating with the health regulator to bring extencilline into the United States to address syphilis drug shortages, according to a letter on the FDA's website.
>
> In June, Pfizer (PFE.N) had warned that it would soon run out of supply of its drug, Bicillin L-A, used to treat syphilis and other bacterial infections in children because it has had to prioritize versions made for adults due to a spike in syphilis infections in that population at the time.
>
> Pfizer's penicillin products have been in shortage since April, according to the FDA's website. According to a survey from August, nearly a third of U.S. hospital pharmacists said that they were forced to ration, delay or cancel treatments as drug shortages in the country approach an all-time high.
>
> Delbert's extencilline, a form of penicillin, is not approved in the United States.

Pandemic-Era Demand for ADHD Meds Is Fueling Shortages Today

U.S. News & World Report reported:

> A spike in the use of ADHD medications during the pandemic likely prompted drug shortages that continue to frustrate patients and doctors today, a new study shows.
>
> New prescriptions for stimulants that treat the condition jumped for young adults and women in particular after the pandemic first struck in March 2020, according to a study published Jan. 10 in the journal JAMA Psychiatry.
>
> Meanwhile, prescriptions also soared for non-stimulant ADHD treatments for adults of all ages, found researchers led by Grace Chai. She's at the Office of Surveillance and Epidemiology at the U.S. Food and Drug Administration's Center for Drug Evaluation and Research.
>
> Why the surge? The mental and emotional strain of the pandemic, coupled with an increased use of telemedicine that made it easier for patients to get help, were big contributors, experts said.

Courts Will Decide the Future of Medicare's Power to Negotiate Drug Prices Within Months

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STAT News reported:

> Pharmaceutical companies' efforts to scuttle President Biden's signature health care achievement, empowering Medicare to negotiate prescription drug prices, will soon face their first big tests.
>
> District court judges could soon weigh in on the litany of court cases that major companies filed against the government — shedding light on whether drugmakers have any hope of postponing the first parts of the negotiation process, scrapping it entirely, or sending the issue up to the Supreme Court.

Oxford Starts Human Testing of Nipah Virus Vaccine

Reuters reported:

> The University of Oxford said on Thursday it had begun human testing of an experimental vaccine against the brain-swelling Nipah virus that led to outbreaks in India's Kerala state and other parts of Asia.
>
> There is no vaccine yet for the deadly virus. Nipah was first identified about 25 years ago in Malaysia and has led to outbreaks in Bangladesh, India and Singapore.
>
> The first participants in the Oxford trial received doses of the vaccine over the last week. The shot is based on the same technology as the one used in AstraZeneca (AZN.L) and Serum Institute of India's COVID-19 shots.

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The Defender Staff

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Best Newest Oldest

Jennifo
8 hours ago

Polio?? Nipah virus??? Who in the sam hell signs up for these shots??? I just cannot fathom what rock people are living under these days? Do they not have eyes & ears??

1 0 Reply • Share ›

CastleConnell
18 hours ago

Gee, prequalified novel nOPV2 shot under emergency use listing by WHO (Gates essentially). The template has been established, EUA for clot shots, and let's continue with any other shot we want to disseminate. Gates is on a roll, and he doesn't understand physiology, he thinks the body is a machine, so he will lead in the destruction of humanity's health. He should invest in clean water, nutrition, and education in third world countries, and he would see mortality rates go down from infectious disease.

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> **brbg** → CastleConnell
> 3 hours ago
>
> Gates' aim is depopulation, not the health of humanity.
>
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drw22
20 hours ago

It's standard procedure for companies that purchase large quantities of given products or parts to negotiate a good deal. Our government should be able to do that also. Not just with drugs.

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drw22
21 hours ago

I thought all recent cases of polio were caught from a child who had a recent polio vaccination. There seems no point to give an EUA to a "new" polio vaxx. In fact, it seems illegal since polio is far from an epidemic

Children's Health Defense

Children's Health Defense® is a 501(c)(3) non-profit organization. Our mission is to end childhood health epidemics by working aggressively to eliminate harmful exposures, hold those responsible accountable and establish safeguards to prevent future harm. We fight corruption, mass surveillance and censorship that put profits before people as well as advocate for worldwide rights to health freedom and bodily autonomy.

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